30. (amended) The vaccine of claim 28 wherein [the] said portion is encapsulated in a liposome or coupled to a liposome.

34. (amended) A pharmaceutical or veterinary vaccine for eliciting an antitumor immune response to prostate tumors in a subject which comprises [as active] an ingredient which is active to elicit said immune response, is formulated for parenteral administration, and comprises at least one antigen overrepresented on the prostate gland with respect to other tissues with the proviso that said antigen is other than human prostate specific antigen (PSA) in a form which is produced in human cells.

36. (amended) The vaccine of claim 34 wherein said antigen is selected from the group consisting of PSA, PSMA, PAP and [a] an immunologically effective portion thereof.

Remarks

The specification and claims have been amended in response to the various objections and rejections. In particular, claims 8, 15, 21, 22, 28 and 34 have been amended to point out more clearly that the active ingredient is formulated for parenteral administration, and to spell out what the activity is. Support for these amendments is found on page 16, lines 1-18 and page 5, lines 28-30 as well as by the characterization of the active ingredient as an antigen which automatically implies that an immune response will be generated. Accordingly, no new matter has been added and entry of the amendment is respectfully requested.

Claims

1. A method to induce an antitumor immune response in a potential or actual prostate tumor-bearing subject which method comprises administering to said subject a composition comprising an active ingredient selected from the group consisting of

at least one antigen overrepresented in the prostate gland or an immunologically effective portion thereof;

an expression system capable of generating *in situ* said antigen; and

an antiidiotypic antibody or fragment thereof which mimics said antigen.

2. The method of claim 1 wherein said antigen in a protein or peptide.

3. The method of claim 2 wherein said protein or peptide is selected from the group consisting of PSA, PSMA, PAP and a fragment thereof.

4. The method of claim 1 wherein said subject is afflicted with metastatic prostate cancer.

5. The method of claim 1 wherein said subject has been surgically treated to excise said tumor but is at risk for recurrence.

6. The method of claim 1 wherein said subject is in a "neoadjuvant" setting prior to surgical excision of said prostate tumor.

7. The method of claim 1 wherein said subject is a potential prostate tumor-bearing subject at risk for said tumor.

8. A pharmaceutical or veterinary vaccine for eliciting an antitumor immune response to prostate tumors in a subject which comprises as active ingredient an expression system capable of generating *in situ* an antigen overrepresented on the prostate gland with respect to other tissues or an immunologically effective portion thereof.

9. The vaccine of claim 8 wherein said antigen is selected from the group consisting of PSA, PSMA, PAP and a portion thereof.

10. The vaccine of claim 8 wherein the antigen is encapsulated in a liposome or coupled to a liposome.

11. The vaccine of claim 10 wherein said liposomes contain an adjuvant or are precipitated with alum.

12. The vaccine of claim 8 which further includes at least one adjuvant capable of enhancing said antitumor immune response.

13. The vaccine of claim 12 wherein said adjuvant is selected from the group consisting of Freund's complete adjuvant; alum; lipid A; monophosphoryl lipid A; *Bacillus Calmette-Guerin* (BCG) or other bacteria; polysaccharides; saponins; detoxified endotoxin (DETOX); muramyl tripeptide or muramyl dipeptide or their derivatives; SAF1; lymphokines; cytokines; colony stimulating factors; nonionic block copolymers; and immune stimulating complexes (ISCOMS).

14. The vaccine of claim 8 wherein said expression system consists essentially of DNA encoding said antigen or portion or wherein said expression system comprises a living expression vector.

15. A pharmaceutical or veterinary vaccine for eliciting an antitumor immune response to prostate tumors in subject which comprises as active ingredient an antiidiotypic antibody or fragment thereof which mimics an antigen overrepresented on the prostate gland with respect to other tissues or an immunologically effective portion thereof.

16. The vaccine of claim 15 wherein said antigen is selected from the group consisting of PSA, PSMA, PAP and a portion thereof.

17. The vaccine of claim 15 wherein the antigen is encapsulated in a liposome or coupled to a liposome.

18. The vaccine of claim 17 wherein said liposomes contain an adjuvant or are precipitated with alum.

19. The vaccine of claim 15 which further includes at least one adjuvant capable of enhancing said antitumor immune response.

20. The vaccine of claim 19 wherein said adjuvant is selected from the group consisting of Freund's complete adjuvant; alum; lipid A; monophosphoryl lipid A; *Bacillus Calmette-Guerin* (BCG) or other bacteria; polysaccharides; saponins; detoxified endotoxin (DETOX); muramyl tripeptide or muramyl dipeptide or their derivatives; SAF1; lymphokines; cytokines; colony stimulating factors; nonionic block copolymers; and immune stimulating complexes (ISCOMS).

21. A pharmaceutical or veterinary vaccine for eliciting an antitumor immune response to prostate tumors in a subject which comprises as active ingredient

at least one antigen overrepresented on the prostate gland with respect to other tissues or an immunologically effective portion thereof,

wherein said active ingredient is encapsulated in or coupled to a liposome.

22. A pharmaceutical or veterinary vaccine for eliciting an antitumor immune response to prostate tumors in a subject which comprises at least two active ingredients each selected from the group consisting of

an antigen overrepresented on the prostate gland with respect to other tissues or an immunologically effective portion thereof;

an expression system capable of generating *in situ* said antigen or portion; and

an antiidiotypic antibody or fragment thereof which mimics said antigen or portion.

23. The vaccine of claim 22 wherein said antigen is selected from the group consisting of PSA, PSMA, PAP and a portion thereof.

24. The vaccine of claim 22 wherein the antigen is encapsulated in a liposome or coupled to a liposome.

25. The vaccine of claim 24 wherein said liposomes contain an adjuvant or are precipitated with alum.

26. The vaccine of claim 22 which further includes at least one adjuvant capable of enhancing said antitumor immune response.

27. The vaccine of claim 26 wherein said adjuvant is selected from the group consisting of Freund's complete adjuvant; alum; lipid A; monophosphoryl lipid A; *Bacillus Calmette-Guerin* (BCG) or other bacteria; polysaccharides; saponins; detoxified endotoxin (DETOX); muramyl tripeptide or muramyl dipeptide or their derivatives; SAF1; lymphokines; cytokines; colony

stimulating factors; nonionic block copolymers; and immune stimulating complexes (ISCOMS).

28. A pharmaceutical or veterinary vaccine for eliciting an antitumor immune response to prostate tumors which comprises as active ingredient at least one immunologically effective portion of an antigen overrepresented on the prostate gland with respect to other tissues said portion being less than the complete antigen.

29. The vaccine of claim 28 wherein said antigen is selected from the group consisting of PSA, PSMA, PAP.

30. The vaccine of claim 28 wherein the portion is encapsulated in a liposome or coupled to a liposome.

31. The vaccine of claim 30 wherein said liposomes contain an adjuvant or are precipitated with alum.

32. The vaccine of claim 28 which further includes at least one adjuvant capable of enhancing said antitumor immune response.

33. The vaccine of claim 32 wherein said adjuvant is selected from the group consisting of Freund's complete adjuvant; alum; lipid A; monophosphoryl lipid A; *Bacillus Calmette-Guerin* (BCG) or other bacteria; polysaccharides; saponins; detoxified endotoxin (DETOX);

muramyl tripeptide or muramyl dipeptide or their derivatives; SAF1; lymphokines; cytokines; colony stimulating factors; nonionic block copolymers; and immune stimulating complexes (ISCOMS).

34. A pharmaceutical or veterinary vaccine for eliciting an antitumor immune response to prostate tumors in a subject which comprises as active ingredient at least one antigen overrepresented on the prostate gland with respect to other tissues with the proviso that said antigen is other than human prostate specific antigen (PSA) produced in human cells.

35. The vaccine of claim 34 wherein said antigen is PSA recombinantly produced in nonhuman cells and exhibits posttranslational modifications different from those of PSA produced in human cells.

36. The vaccine of claim 34 wherein said antigen is selected from the group consisting of PSA, PSMA, PAP and a portion thereof.

37. The vaccine of claim 34 wherein the antigen is encapsulated in a liposome or coupled to a liposome.

38. The vaccine of claim 37 wherein said liposomes contain an adjuvant or are precipitated with alum.

39. The vaccine of claim 34 which further includes at least one adjuvant capable of enhancing said antitumor immune response.

40. The vaccine of claim 39 wherein said adjuvant is selected from the group consisting of Freund's complete adjuvant; alum; lipid A; monophosphoryl lipid A; *Bacillus Calmette-Guerin* (BCG) or other bacteria; polysaccharides; saponins; detoxified endotoxin (DETOX); muramyl tripeptide or muramyl dipeptide or their derivatives; SAF1; lymphokines; cytokines; colony stimulating factors; nonionic block copolymers; and immune stimulating complexes (ISCOMS).

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Abstract

Vaccines capable of eliciting an immune antitumor response for prostate tumors are disclosed. The active ingredient in such vaccines is selected from the group consisting of

at least one antigen overrepresented in the prostate gland or an immunologically effective portion thereof;

an expression system capable of generating *in situ* said antigen or portion; and

an antiidiotypic antibody or fragment thereof which mimics said antigen or portion.